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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,886	09/30/2003	Jean-Louis Escary	60711.000023	7856

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EXAMINER	
JOHANNSEN, DIANA B	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/673,886	ESCARY, JEAN-LOUIS	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-113* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-113* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-78, drawn to nucleic acids, vectors, and host cells, classified in class 536, subclass 23.1, and class 435, subclasses 252.3, 320.1, and 325.

II. Claim 79, drawn to therapeutic agents, classified in class 514, subclass 44.

III. Claims 80-82, drawn to diagnostic methods employing nucleic acids, classified in class 435, subclass 6.

IV. Claims 83-102, drawn to proteins, classified in class 530, subclass 350.

V. Claims 103-106, drawn to therapeutic proteins and methods, classified in class 514, subclass 2.

VI. Claim 107, drawn to antibodies, classified in class 530, subclass 387.1.

VII. Claims 108-111, drawn to therapeutic antibodies and methods, classified in class 424, subclass 130.1.

VIII. Claims 112-113, drawn to screening methods, classified in class 435, subclass 7.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I-II and IV-VII are drawn to patentably distinct products. The polynucleotides of Invention I are composed of nucleotides and function in methods of, e.g., hybridization. While the products of Invention II are also composed of nucleotides, these products comprise additional elements necessary for therapeutic function and

function in, e.g., therapy. The proteins of Invention IV are composed of amino acids and function in, e.g., binding assays. Although the products of Invention V are also composed of amino acids, these have additional structural features and functional capabilities not required of the proteins of Invention IV. The antibodies of Invention VI are composed of amino acids present in a particular form (e.g., multiple heavy and light chains containing constant and variable regions), and function in, e.g., protein detection. Although the products of Invention VII also comprise antibodies, these antibodies have additional structural features and functional capabilities not required of the products of Invention VI. Further, each of these Inventions would require a separate text search employing different terms to identify relevant art, and has a separate status in the art as shown by different classifications. Accordingly, searching more than one of these Inventions would impose a serious burden.

Inventions III and VIII are patentably distinct methods having different objectives and requiring the use of different reagents in different process steps. Invention III requires, e.g., steps of nucleic acid hybridization to achieve the objective of genotyping. Invention VIII requires determining the effect of compounds on cellular activity to achieve the objective of identifying compounds with a particular activity. The inventions require text searches using different terms aimed at identifying different types of prior art, and have a separate status in the art as shown by their different classifications. Accordingly, searching more than one of these Inventions would impose a serious burden.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the products of Invention I may be used in materially different processes, such as methods of genomic mapping. Additionally, the Inventions require different text searches, and have a separate status in the art as shown by their different classifications. A search of more than one of the Inventions would therefore pose a serious burden.

Inventions I and VIII are unrelated because the products of Invention I are not used or otherwise involved in the processes of Invention VIII.

Inventions II and III, and II and VIII, are unrelated because the products of Invention II are not used or otherwise involved in the processes of Inventions III or VIII.

Inventions III and IV, III and V, III and VI, and III and VII, are unrelated because the products of Inventions IV, V, VI and VII are not used or otherwise involved in the processes of Invention III.

Inventions IV and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the products of Invention IV may be used in materially different processes, such as methods of

making antibodies. Additionally, the Inventions require different text searches, and have a separate status in the art as shown by their different classifications. A search of more than one of the Inventions would therefore pose a serious burden.

Inventions V and VIII, VI and VIII, and VII and VIII, are unrelated because the products of Inventions V, VI and VII are not used or otherwise involved in the processes of Invention VIII.

3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification and recognized divergent subject matter, and because Inventions I-VIII require different searches that are not co-extensive, a search of more than one of Inventions I-VIII would pose a serious burden on the examiner, and therefore restriction for examination purposes as indicated is proper.

Species election

4. This application contains claims directed to the following patentably distinct species:

a) With regard to Groups I-III, the multitude of distinct SNP-containing polynucleotides encompassed by the claims. Each such polynucleotide and polynucleotide is characterized by a different set of structural and functional properties, and each such polynucleotide would require a different sequence search. Accordingly, a search of more than one such polynucleotide would impose a serious burden. If any of Groups I-III is elected, Applicant is therefore

required to elect a single polynucleotide for examination. The SNPs present in the elected molecule(s) should be specified.

b) With regard to Groups IV-VI and VIII, the multitude of distinct polypeptides encompassed by the claims. Each such polypeptide is characterized by a different set of structural and functional properties, and each such polypeptide would require a different sequence search. Accordingly, a search of more than one such polypeptide would impose a serious burden. If any of Groups IV-VI and VIII is elected, Applicant is therefore required to elect a single polypeptide for examination. The variant amino acids present in the elected polypeptide(s) should be specified.

c) With regard to Groups VI and VII, the multitude of distinct antibodies encompassed by the claims, which antibodies are specific for the polypeptides noted immediately above in b). Each such antibody is characterized by a different set of structural and functional properties, and each such antibody would require a different sequence search. Accordingly, a search of more than one such antibody would impose a serious burden. If any of Groups VI and VII is elected, Applicant is therefore required to elect a single antibody for examination. The variant amino acids present in the target polypeptide(s) for the elected antibody should be specified.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (as indicated above) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims

and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Diana B. Johannsen
Primary Examiner
Art Unit 1634